

In re Application of: Michal DANIELY et al
Serial No.: 10/771,440
Filed: February 5, 2004
Final Office Action Mailing Date: December 11, 2008

Examiner: Bradley DUFFY
Group Art Unit: 1643
Attorney Docket: 26003

In the Claims:

1-71. (Cancelled)

72. (Currently Amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

(a) staining nucleated cells of the urine sample using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou and Hematoxylin-Eosin to thereby obtain stained nucleated cells, ~~so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma and subsequently;~~

(b) imaging said stained nucleated cells resultant of step (a) so as to obtain images of said stained nucleated cells; ~~and subsequently;~~

(c) identifying in said images of step (b) a single cell having a morphological abnormality associated with transitional cell carcinoma, and subsequently;

(ed) staining said stained nucleated cells resultant of step (a) using fluorescent *in situ* hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, ~~so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell;~~ and subsequently;

(de) imaging said stained nucleated cells stained with FISH resultant of step (ed) so as to obtain images of said stained nucleated cells stained with FISH; ~~and subsequently;~~

(f) identifying in said images of step (e) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (c) having said morphological abnormality associated with transitional cell carcinoma;

(e) ~~simultaneously viewing said images resultant of steps (b) and (d), and;~~

(f) ~~identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of said morphological abnormality and said chromosomal abnormality in the same said~~

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single cell indicates that said same single cell is indicative of a presence of a cancerous cell

thereby identifying the transitional cell carcinoma cells in the urine sample.

73. (Currently Amended) A method of diagnosing bladder cancer in a subject, the method comprising:

(a) obtaining a urine sample from the subject;

(b) staining nucleated cells of said urine sample using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou and Hematoxylin-Eosin to thereby obtain stained nucleated cells, so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma and subsequently;

(c) imaging said stained nucleated cells resultant of step (b) so as to obtain images of said stained nucleated cells; and subsequently;

(d) identifying in said images of step (c) a single cell having a morphological abnormality associated with transitional cell carcinoma, and subsequently;

(de) staining said stained nucleated cells resultant of step (b) using fluorescent *in situ* hybridization (FISH) to thereby obtain stained nucleated cells stained with FISH, so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell, and subsequently

(ef) imaging said stained nucleated cells stained with FISH resultant of step (de) so as to obtain images of said nucleated cells stained with FISH; and subsequently;

(g) identifying in said images of step (f) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (d) having said morphological abnormality associated with transitional cell carcinoma, (f) simultaneously viewing said images resultant of steps (e) and (e), and;

(f) identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of

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said morphological abnormality and said chromosomal abnormality in the same said single cell indicates that said same single cell is is indicative of a presence of a cancerous cell;

wherein said presence of said cancerous cell is indicative of a positive cancer diagnosis.

74-81. (Cancelled)

82. (New) The method of claim 72, wherein the transitional cell carcinoma cells are associated with bladder cancer or kidney cancer.

83. (New) The method of claim 72, wherein the urine sample is obtained via voided urine or catheterization.

84. (New) The method of claim 72, wherein said imaging is effected using an automated cell imaging device capable of at least dual imaging.

85. (New) The method of claim 73, wherein the urine sample is obtained via voided urine or catheterization.

86. (New) The method of claim 73, wherein said imaging is effected using an automated cell imaging device capable of at least dual imaging.